Office Action Summary	Application No. 08/948393	Applicant(s) WAGNER ET AL.
	Examiner GAMBEL	Art Unit 1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, ~~may a reply~~ be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☑ ~~This~~ action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1-24, 28-30, 35-38, 40, 42-85

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5, 15, 16, 18-20, 23, 28-30, 38, 40, 44, 46, 47, 53, 58, 59, 68-70

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 1-4, 6-14, 17, 21, 22, 24, 35-37, 42, 43(45), 48-52, 54-57, 60-67, 71-85

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 1/17/02 (Paper No. 43), has been entered.
Claims 71-85 have been added.

Claims 1-24, 28-30, 35-38, 40 and 42-85 are pending.
Claims 25-27, 31-34, 39 and 41 have been canceled previously.

Applicant's election with traverse of Group IV in Paper No. 43 is acknowledged. The traversal is on the ground(s) that the claims specifically states that the therapeutic agents is used to treat atherosclerosis and that without concrete evidence to support other uses of the therapeutic agents, any suggestion that the therapeutic agents may have such uses is clearly speculative and without foundation. In contrast to applicant's apparent reliance on the disclosure of the instant specification, the claimed agents, including the agent employed in the elected invention can be used in various inflammatory conditions. For example, see Cummings et al. (U.S. Patent No. 5,464,778; Clinical Applications on columns 18-21. Also, see Larsen et al. (U.S. Patent No. 5,840,679; columns 15-16, overlapping paragraph). Regarding applicant's comments about undue burden and common classification, the MPEP 803 states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". Individual antagonists and agonists that do not share a substantial structural feature essential to a common utility are subject to restriction, rather than election of species within the context of the particular method The Restriction Requirement enunciated in the previous Office Action meets this criterion and therefore establishes that the inventions are distinct and require non-coextensive searches.
The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4, 6-14, 17, 21, 22, 24, 35-37, 42, 43, (45), 48-52, 54-57, 60-67 and 71-85 are under consideration as they read on the elected invention, drawn to methods of treating or inhibiting atherosclerosis with PSGL-1, fragments and chimeric constructs thereof.
For examination purposes, the use of PSGL-1, fragments and chimeric constructs thereof have the inherent property of inhibiting L- / E-selectin-mediated interactions. If applicant disagrees with this assessment, then such claims would be removed from consideration as they on the elected invention.
Also, analogs of PSGL 1 read on fragments and chimeric constructs thereof.
If applicant disagrees with this assessment, then such claims would be removed from consideration as they on the elected invention
For examination purposes, PSGL "on a leukocyte" (e.g. neutrophil, monocyte) reads on PSGL and not on the administration of cells per se.

Claims 1-24, 28-30, 35-38, 40 and 42-47, 52, 53, 55-59, 70 as they read on methods of treating or inhibiting atherosclerosis with agents other than PSGL-1 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Applicant is invited to provide a complete set of the pending claims for clarity, and preferably applicant is invited to amend or to cancel/add claims as they read on methods of treating or inhibiting atherosclerosis with PSGL-1 for clarity. The pending claims are spread over a number of amendments. Further, the claims have been restricted into Groups.

2. Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents. USSN 08/377,798 is now abandoned.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

5. Claim 71 is objected to because it ends with two periods (" .. ").

6. Claims 74-75 are objected to under 37 CFR 1.75 as being a substantial duplicates of one another. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

7. Claims 80 is objected to because "leu8kocyte" should be "leukocyte"

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Written Description: New Matter:

Claims 50, 51, 60-67 and 71-85 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "chimeric constructs of PSGL-1".

Applicant's amendment, filed 1/17/02 (Paper No. 43), did not provide direction for the written description for the above-mentioned "limitations" for the newly added claims 71-85

Applicant's amendment, filed 11/8/99 (Paper No. 28) , directs support to various sections of the instant specification (pages 3-4, 8-12); however the written description of "chimeric constructs of PSGL-1" is not readily apparent from the specification as filed.

The specification as filed does not provide a written description or set forth the metes and bounds of "chimeric constructs of PSGL-1". The specification does not provide sufficient blazemarks nor direction for the instant methods encompassing the above-mentioned "limitation", as it is currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06

10. Written Description:

Claims 50, 51, 60-67 and 71-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims recite "chimeric construct of P-selectin ligand", including with "another molecule". As pointed out above, the written description of "chimeric construct of P-selectin ligand" is readily apparent in the specification. In addition, it is not readily apparent what is the nature of the chimeric construct, including the nature of "another molecule". For example, "PSGL-1" is chimeric with what molecule? The instant disclosure does not provide sufficient characteristics or identify members of the genus of "chimeric constructs of P-selectin ligand", including "another molecules". The instant claims do not provide functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, "chimeric constructs of PSGL-1" with "another molecule" alone is insufficient to describe the genus of either the claimed chimeric molecules.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Thus, the specification fails to describe these DNA sequences. The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of "chimeric constructs of PSGL-1", including with "another molecule"; one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

11. Claims 13, 24, 42, 43, (45), 48-52, 60-67 and 71-81, 83-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "fragments that inhibit the interaction between P-selectin and PSGL-1" and "analogs that read on "PSGL-1" or "fragments that inhibit the interaction between P-selectin and PSGL-1", does not reasonably provide enablement for any "fragment" or "analog" of PSGL The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies "fragments" and "analogs" nor sufficient information that would enable that any "fragment" of "analog" of PSGL-1 would be effective or predictive of treating atherosclerosis.

Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functionality (e.g. inhibit atherosclerosis) requires a knowledge of and guidance with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which a polypeptide's structure relates to its functional usefulness. However, the problem of predicting polypeptide structure from mere sequence data of a single amino acid sequence and in turn utilizing predicted structural determinations to ascertain binding or functional aspects "PSGL-1 fragments and analogs" and finally what changes can be tolerated with respect thereto is complex and well outside the realm of routine experimentation.

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant application, it is noted that various mutations, substitutions and the like provide a range of activities, no all which are necessarily predictive of "PSGL-1 fragments and analogs to treat atherosclerosis". It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different pharmacological activities.

A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance to direct a person of skill in the art to select particular sequences as essential for in vivo characterization of their therapeutic potential to treat atherosclerosis. A person of skill in the art could not predict which particular amino acid sequences of "PSGL-1" are essential to "fragments and analogs" and could be used in a therapeutic methods.

The success of state of the art structure-based strategies for inhibitor design is highly unpredictable. For example, Kuntz (Science 257:1078-1082, 1992) on page 1080, column 3, discloses that as little as 2% of compounds predicted to inhibit specific enzymatic or receptor systems actually show inhibition in the micromolar range. Kuntz further discloses that "optimization" of these compounds has proven even more problematic. Therefore, in view of the unpredictability in the art, and in view of the insufficient guidance and working examples in the specification, the quantity of experimentation required by one skilled in the art to practice the invention undue.

Because of the lack of sufficient guidance and predictability in determining which modifications would lead to "PSGL-1 fragments and analogs to treat atherosclerosis" and that the relationship between the sequence of a protein / peptide and its tertiary structure (i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al., in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of other functional PSGL-1 fragments

and analogs to treat atherosclerosis".

Without sufficient guidance, the changes which can be made in the structure of "PSGL-1 fragments and analogs to treat atherosclerosis" is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-4, 6-14, 17, 21, 22, 24, 44, (45), 48, 49, 52, 54, and 71-82 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cummings et al. (U.S. patent No. 5,464,778) (see entire document). Cummings et al. teach the use of PSGL in the treatment of leukocyte adherence, inflammation and coagulation, including ischemia-reperfusion injury and atherosclerosis (see column 18, paragraphs 5-8; columns 19-20, overlapping paragraph). Cummings et al. teach the properties and the use of PSGL (column 9-18), including protein fragments thereof (e.g. column 20, paragraph 3) as well as the administration and monitoring according to one of ordinary skill in the art (column 21, paragraphs 2-3) . Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations (e.g. inhibiting L-/E-selectin-mediated interactions) would be inherent properties of the referenced methods of treating atherosclerosis with PSGL and fragments thereof and the properties of said PSGL and fragments thereof. For examination purposes, PSGL "on a leukocyte" (e.g. neutrophil, monocyte) reads on PSGL and not on the administration of cells per se.

Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). See MPEP 2112-2112.02.

15. Claims 1-4, 6-14, 17, 21, 22, 24, 35-37, 42, 43, (45), 48-52, 54-57, 60-67 and 71-85 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cummings et al. (U.S. patent No. 5,464,778) in view of Larsen et al. (U.S. Patent No. 5,840,679).

Cummings et al. teach the use of PSGL in the treatment of leukocyte adherence, inflammation and coagulation, including ischemia-reperfusion injury and atherosclerosis (see column 18, paragraphs 5-8; columns 19-20, overlapping paragraph). Cummings et al. teach the properties and the use of PSGL (column 9-18), including protein fragments thereof (e.g. column 20, paragraph 3) as well as the administration and monitoring according to one of ordinary skill in the art (column 21, paragraphs 2-3). The claimed functional limitations would be expected properties of the referenced methods of treating atherosclerosis with PSGL and fragments thereof.

Larsen et al. teach the use of PSGL (e.g. ; columns 7-8, columns 13-18 and Examples), including fragments (e.g. columns 9-10) and fragments fused to carrier molecules such as immunoglobulins (e.g. chimeric forms of said PSGL (column 9-10, overlapping paragraph) to treat conditions characterized by P- or E-selectin mediated intercellular adhesion, such as myocardial infarction (columns 15-16, overlapping paragraph), including its combination with other pharmaceutical compositions, including anti-inflammatory and thrombolytic or anti-thrombotic agents (e.g. columns 16-18) (see entire document, including Summary of the Invention; Detailed Description of the Invention). Larsen et al. also teach various modes of administration and dosing (e.g. liposomes, pharmaceutical carriers), including combinations of agents would be provided in therapeutically effective amounts either serially or simultaneously sufficient for the needs of the patient, including the nature and severity of the condition being treated according to the attending physician (columns 16-18).

Therefore, Larsen et al. teach the art known use controlled release systems, combination therapy. Also, Given the teachings of both Cummings et al. and Larsen et al.; the ordinary artisan would have provided therapeutic amounts of PSGL-, fragments and chimeric constructs thereof to meet the severity of the condition and the needs of the patients. Therefore, the modes of administration and dosages encompassed by the claimed invention would have been met by the ordinary artisan at the time the invention was made to meet the severity of the condition and the needs of the patients (e.g. claims 35, 42-43, 55-57, 62, 65-67, 83-85).

Given the prior art teaching of inhibiting atherosclerosis as well as reperfusion-ischemia injury, the prior art methods would have had the expected property of "at least partially reversing a formed atherosclerotic intermediate lesion, atherosclerotic fatty streak or atherosclerotic fibrous plaque" (e.g. claims 28-29, 35).

For examination purposes, the use of PSGL-1, fragments and chimeric constructs thereof have the intrinsic or expected property of inhibiting L- / E-selectin-mediated interactions. Given the properties of PSGL, fragments and chimeric constructs thereof as taught by Cummings et al. and Larsen et al. As inhibitors of PSGL-mediated interactions and as anti-inflammatory reagents; use of PSGL-1, fragments and chimeric constructs thereof have the intrinsic or expected property of inhibiting L- / E-selectin-mediated interactions (e.g. 38, 45, 63, 64) .

For examination purposes, PSGL "on a leukocyte" (e.g. neutrophil, monocyte) reads on PSGL and not on the administration of cells per se (e.g. claims 8-11, 77-80).

For examination, analogs of PSGL-1 read on fragments and chimeric constructs thereof, as taught by Cummings et al. and Larsen et al. (e.g. claims 24, 58)

One of ordinary skill in the art at the time the invention was made would have been motivated to administer PSGL-1, fragments and chimeric constructs thereof, provided they had the properties of inhibiting PSGL-1-mediated interactions and inflammatory responses, as taught by Cummings et al. And Larsen et al. to treat patients with atherosclerosis. Given the teachings of Cummings et al. to treat atherosclerosis per se and of both Cummings et al. and Larsen et al. to inhibit PSGL-1-mediated interactions and inflammatory responses, including those associated with coronary/thrombotic conditions, the ordinary artisan would have had a reasonable expectation of success at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-4, 6-14, 17, 21, 22, 24, 35-37, 42, 43, (45), 48-52, 54-57, 60-67 and 71-85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 40-41, 45, 49-52, 56, 59-60, 3-74 as they read on the use of PSGL-1 to treat atherosclerosis of copending application Serial No. 09/436,076 and

claims 39-88 as they read on the use of PSGL-1 to treat atherosclerosis of copending application USSN 09/883,642.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same methods of treating atherosclerosis with the same or nearly the same PSGL-1, fragments and chimeric constructs thereof.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
April 8, 2002